K003794

MAR 3 0 2001

SUMMARY OF 510 (k) SAFETY AND EFFECTIVENESS INFORMATION

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92.

Micro Detect, Inc. PYLORI DETECT IgA reagents (P/N: HpKi-A) is intended for the qualitative determination of IgA antibodies to *H. pylori* in human serum. The principal diagnostic value of this assay is detection of IgA antibodies to *H. pylori*, which is used as an aid in patients with Gastric Cancer, Peptic and Duodenal ulcers. This test should be used in conjunction with PYLORI DETECT IgG which detects IgG antibodies to *H. pylori* in human serum.

The Micro Detect, Inc. *H. pylori* reagent (PYLORI DETECT IgA) is intended to be used as a manual procedure. The reagents are supplied as a micro plate coated with specific *H. pylori* antigens, Controls, Wash Buffer, Sample Diluent, Conjugate, Substrate, and Stop Solution.

The patient results obtained using the PYLORI DETECT IgA are substantially equivalent to those obtained by endoscopic evaluations:

Sensitivity:	62.5%*
Specificity:	94.3 %
Positive predictive value:	95.4 %
Negative predictive value:	56.8 %
Accuracy:	73.5 %

Precision (% C.V.): 2.81-7.94 (Inter) and 4.19-7.61 (Intra)
Precision (% C.V.)**: 9.56 (Inter) and 2.6-3.5 (Intra)

Stability: One year at 2-8°C. The stability of the PYLORI DETECT IgA Kit for the detection of IgA antibodies to *H. pylori* was found to be one year at 2-8°C. This was predicted from studies done under stress condition (37°C).

The micro plate ELISA formats is a commonly used format for the detection of many entities of clinical interest, including infectious diseases.

The PYLORI DETECT IgA assay system is shown to be safe and effective providing results, which are substantially equivalent to those obtained by endoscopic evaluations.

* Low sensitivity is not because of the product performance. It is due to the fact that a number of *H. pylori* positive patients are negative for IgA.

** Determined in three independent labs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 3 0 2001

Mehdi Alem, Ph.D.,
President
Micro Detect, Inc.
2852 Walnut Avenue, Suite H-1
Tustin, CA 92780

Re: K003794
Trade Name: Pylori Detect IgA
Regulatory Class: I
Product Code: LYR
Dated: March 14, 2001
Received: March 15, 2001

Dear Dr. Alem:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K003794/A1

510(k) Number (if known): K003794

Device Name: PYLORI DETECT IgA

Indications For Use:

The PYLORI DETECT IgA is a qualitative enzyme immunoassay (EIA) kit for the detection of IgA antibodies against *H. pylori* in human serum. The test is to be used as a second test in the diagnosis of infection by *H. pylori* in patients with gastrointestinal symptoms. The PYLORI DETECT IgA should be performed and interpreted in conjunction with the PYLORI DETECT IgG for detection of antibodies to *H. pylori*.
FOR *in vitro* DIAGNOSTIC USE ONLY

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003794

Prescription Use X
(Per 21 CFR 801,109)

OR

Over-The-Counter Use___

(Optional Format 1-2 -96)

SK 27